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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,812	02/25/2002	James W. Simpkins	1540/144	2471

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EXAMINER	
WEDDINGTON, KEVIN E	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/082,812	SIMPKINS, JAMES W.	
	Examiner	Art Unit	
	Kevin E. Weddington	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4* is/are rejected.

7)☒ Claim(s) *2 and 3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11-24-03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-4 are presented for examination.

Applicants' request for continued examination and information disclosure statement filed November 24, 2003 have been received and entered.

Claim Objections

Claims 2 and 3 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19of U.S. Patent No. 6,326,365. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application teaches a

method for mitigating the effects of a future ischemic event in a subject with the administration of a prophylactic amount of a non-sex hormone; and the patented application teaches methods for treating ischemia, conferring protection on a population of cells associated with an ischemic focus, for protecting cells from degeneration, and treating stroke in a subject with an estrogen compound (a sodium sulfate of estrogen). Clearly, one skilled in the art would have assumed the patented application's method is a prophylactic treatment against ischemia (present or future) since the estrogen compound is used as a cytoprotective agent, then to use the same estrogen compound (non-sex hormone) to prevent future ischemic event is obvious in the absence of evidence to the contrary.

Claim 1 is not allowed.

Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,339,078. Although the conflicting claims are not identical, they are not patentably distinct from each other because present application teaches a method for mitigating the effects of a future ischemic event in a subject with the administration of a prophylactic amount of a non-sex hormone; and the patented application teaches a method conferring protection on a population of cells associated with ischemia in a subject with an estrogen compound. Clearly, one skilled in the art would have assumed the patented application's

method is a prophylactic treatment against ischemia (present or future) since the estrogen compound is used as a cytoprotective agent, then to use the same estrogen compound (non-sex hormone) to prevent future ischemic event is obvious in the absence of evidence to the contrary.

Claim 1 is not allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for mitigating the effects of a future ischemic event in subject with the administration of 17-alpha estradiol or 17-beta estradiol, does not reasonably provide enablement for other non-sex hormones such as estradiol, estrone or estrione. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to a method for mitigating the effects of a future ischemic event in a subject, the method comprising:

(a) identifying a subject having a susceptibility profile associated with an increased risk for experiencing a future ischemic event; and

(b) administering a prophylactic amount of a non-sex hormone to said subject for a time-course duration effective so as to reduce adverse effects of a future ischemic event experienced by said subject.

The relative skill of those in the art is generally that of a Ph.D. or M.D.

The present invention is unpredictable unless experimentation is shown for other non-sex hormones such as estradiol, estrone and estrione to mitigate the effects of a future ischemic event.

The breadth of the claims

The claims are very broad and inclusive to all non-sex hormones

The amount of direction or guidance provided and the presence or absence of working examples

The working examples are limited to the administration of 17-alpha estradiol and 17-beta estradiol.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to how other non-sex hormones such as estradiol, estrone and estrione are effective for mitigating the effects of a future ischemic event in a subject. The level of experimentation needed to determine the other non-sex hormones would be able to mitigate the said ischemic event is undue. Therefore, undue experimentation would be required to practice the invention as it is claimed in its current scope.

Claims 1 and 4 are not allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collins (5,512,557) of PTO1449.

Collins teaches the administration of 17β-oestradiol (a non-sex hormone) to treat coronary heart disease (See the abstract). Note particularly column 2, lines 25-30 states the specific type of coronary heart disease treated is myocardial ischaemia (an ischemic event).

The instant invention differs from the cited reference in that the cited reference does not teach the administration of 17β-oestradiol (a non-sex hormone) is administered to a subject to mitigate the effects of a future ischemic event. However, one skilled in the art would have assumed the use of 17β-oestradiol (known to treat an ischemic condition) as a prophylactic treatment against ischemia (present or future) is obvious in the absence of evidence to the contrary.

The instant invention differs from the cited reference in that the cited reference does not the time-course duration (extend over a plurality of months) the non-sex hormone is administered to said subject. However, it would have been obvious to one skilled in the art at the time the invention was made to modify the method of Collins to administer the said non-sex hormone at a time-course duration wherein the said subject is constantly receiving the non-sex hormone, thus to prevent the reoccurrence of the ischemic event.

Claims 1 and 4 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The

fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
June 16, 2005